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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,559	05/30/2006	Luis Anglada	2294-0125PUS1	8249

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EXAMINER	
MOORE, SUSANNA	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
03/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,559	ANGLADA ET AL.	
	Examiner	Art Unit	
	SUSANNA MOORE	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *33-45 and 47-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/28/06,12/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V in the reply filed on 1/16/2008 is acknowledged. Group I, drawn to pyrazolo[1,5-a]pyrimdines and simple compositions thereof, embraced by claims 1-32 and 46 was elected by Applicant. The traversal is on the ground(s) that "the present claims are linked to form a single general inventive concept under PCT Rule 13.1." This is not found persuasive because the pyrazolo[1,5-a]pyrimidine core presented in Formula (I) is found in US 4654347. Thus, unity is lacking. The requirement is still deemed proper and is therefore made **FINAL**.

In summary, there are fifty one claims pending and thirty three under consideration. Claims 1-12 are compound claims and claim 46 is a composition claim. Claims 33-45 and 47-51 are currently withdrawn, since these claims are drawn to methods of making or using. This is the first action on the merits.

Information Disclosure Statement

The information disclosure statement filed 12/28/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The disclosure is objected to because of the following informalities: the term "prop-2-inyl" is used throughout the Specification. Appropriate correction is required.

Claim Objections

Claim 22 is objected to because of the following informalities: the term "ethanesulfonamida" is misspelled, see line 14. Appropriate correction is required.

Claim 24 is objected to because of the following informalities: the term "cyclopenthylmethansulfonamide" is misspelled, see the last line. Appropriate correction is required.

Claim 25 is objected to because of the following informalities: the term "carbonel" is misspelled, see the last line. Appropriate correction is required.

Claims 22, 24 and 26-32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim does not refer back in the alternative. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11, 13, 15, 19, 21, 22, 24, 26-29, 31, 32 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "prop-2-inyl" and "2-propinyl" are vague. Does Applicant intend "propenyl" or "propynyl?" One of these terms is found in the following places:

Claim 9, line 3; claim 11, line 4; claim 13, line 4; claim 15, line 4; claim 19, line 4; claim 21, line 4; claim 22, lines 12, 18-19 and 33; claim 24, line 11 and 17; claim 26, lines 11 and 13; claim 27, lines 11 and 13; claim 28, lines 11 and 13; claim 29, lines 11 and 13; claim 31, lines 7 and 13; and claim 32, lines 11 and 13.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "in association" is vague. The Specification does not provide any guidance for such a phrase. The Examiner suggest the removal of the phrase "in association" from claim 13.

Claims 1, 2, 5, 8, 10, 12, 14, 16, 18, 20 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "alkyl(C_1-C_6)-O-alkyl(C_1-C_6), alkyl(C_1-C_6)-NH-alkyl(C_1-C_6) and alkyl(C_1-C_6)-N-(dialkyl(C_1-C_6))" are vague. "Alkyl" substituents are trivalent, not divalent. One of the "alkyl" substiuents in these terms should denoted a divalent substituent, if this is what Applicant intends.

Claims 1-21 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of Formula 1, wherein R_1 is selected from the group consisting of alkyl(C_1-C_6), alkenyl(C_2-C_6), trifluoroalkyl(C_1-C_6), cycloalkyl(C_3-C_6), cycloalkyl(C_3-C_6) alkyl(C_1-C_6), phenyl, monosubstituted phenyl, disubstituted phenyl, phenylalkyl(C_1-C_6), phenylalkenyl(C_2-C_6), furyl, substituted furyl, isoxazolyl, substituted isoxazolyl, pyrazolyl, substituted pyrazolyl, thienyl, substituted thienyl, thiazolyl, substituted thiazolyl, pyridyl and substituted pyridyl; R_2 is selected from the group consisting of hydrogen, alkyl (C_1-C_6), alkenyl(C_2-C_6), alkynyl(C_2-C_6) and cycloalkyl(C_3-C_6); R_3 is selected from the group consisting of CN and COR_6 does not provide enablement for compounds of Formula (I) wherein, R_1= O-alkyl(C_1-C_6), NH-alkyl(C_1-C_6), N(dialkyl(C_1-C_6)), alkyl(C_1-C_6)-O-alkyl(C_1-C_6), alkyl(C_1-C_6)-NH-alkyl(C_1-C_6) and alkyl(C_1-C_6)-N-(dialkyl(C_1-C_6)), R_1 and R_2 form a cycle, R_3= hydrogen, halogen, alkyl (C_1-C_2), cycloalkyl(C_3-C_6), alkenyl(C_2-C_6), alkynyl(C_2-C_6), -O-alkyl(C_1-C_6), haloalkyl(C_1-C_6), $S0_2R_4$, NH-R_4, NR_4R_5, CO-NHR_6, $COOR_6$, C(NR7)R_6, phenyl, substituted phenyl, heteroaryl and substituted heteroaryl. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Pursuant to In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of

direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see In re Vaeck, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(A) Breadth of claims: Scope of the compounds. Owing to the range of many variables, trillions of substituted pyrazolo[1,5-a]pyrimidines are embraced.

(B) The nature of the invention: The invention is a highly substituted pyrazolo[1,5-a]pyrimidines.

(C) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(D) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of Formula 1, under Preparation on pages 21-23 of the Specification, but does not show the starting material used to make the variety of compounds claimed. There is limited evidence in the Specification of the example compounds that only cover a small portion of the substituents claimed of Formula 1. Thus, there is no specific direction or guidance regarding said compounds of Formula 1 specifically mentioned in Scope.

The specification does not provide any support for the synthesis of compounds of Formula 1, wherein, R_1= O-alkyl(C_1-C_6), NH-alkyl(C_1-C_6), N(dialkyl(C_1-C_6)), alkyl(C_1-C_6)-O-alkyl(C_1-C_6), alkyl(C_1-C_6)-NH-alkyl(C_1-C_6) and alkyl(C_1-C_6)-N-(dialkyl(C_1-C_6)), R_1 and R_2 form a cycle, R_3= hydrogen, halogen, alkyl (C_1-C_2), cycloalkyl(C_3-C_6), alkenyl(C_2-C_6), alkynyl(C_2-C_6), -O-alkyl(C_1-C_6), haloalkyl(C_1-C_6), $S0_2R_4$, NH-R_4, NR_4R_5, CO-NHR_6, $COOR_6$, $C(NR_7)R_6$, phenyl, substituted phenyl, heteroaryl and substituted heteroaryl.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 21'64.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *In re Ghiron*, 442 F.2d 985, 991,169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(E) State of the Prior Art: These compounds are substituted pyrazolo[1,5-a]pyrimidines of Formula I wherein wherein R_1 is selected from the group consisting of alkyl(C_1-C_6), alkenyl(C_2-C_6), trifluoroalkyl(C_1-C_6), cycloalkyl(C_3-C_6), cycloalkyl(C_3-C_6) alkyl(C_1-C_6), phenyl, monosubstituted phenyl, disubstituted phenyl, phenylalkyl(C_1-C_6), phenylalkenyl(C_2-C_6), furyl, substituted furyl, isoxazolyl, substituted isoxazolyl, pyrazolyl, substituted pyrazolyl, thienyl,

substituted thienyl, thiazolyl, substituted thiazolyl, pyridyl and substituted pyridyl; R_2 is selected from the group consisting of hydrogen, alkyl (C_1-C_6), alkenyl(C_2-C_6), alkynyl(C_2-C_6) and cycloalkyl(C_3-C_6); R_3 is selected from the group consisting of CN and COR_6 which are well documented in the art. So far as the examiner is aware, no substituted pyrazolo[1,5-a]pyrimidines of Formula I wherein, R_1= O-alkyl(C_1-C_6), NH-alkyl(C_1-C_6), N(dialkyl(C_1-C_6)), alkyl(C_1-C_6)-O-alkyl(C_1-C_6), alkyl(C_1-C_6)-NH-alkyl(C_1-C_6) and alkyl(C_1-C_6)-N-(dialkyl(C_1-C_6)), R_1 and R_2 form a cycle, R_3= hydrogen, halogen, alkyl (C_1-C_2), cycloalkyl(C_3-C_6), alkenyl(C_2-C_6), alkynyl(C_2-C_6), -O-alkyl(C_1-C_6), haloalkyl(C_1-C_6), $S0_2R_4$, NH-R_4, NR_4R_5, CO-NHR_6, $COOR_6$, C(NR7)R_6, phenyl, substituted phenyl, heteroaryl and substituted heteroaryl of any kind have been made or used.

(F) Working Examples: Applicant shows example 1-923 and 1143-1146 but no working examples were shown of Formula I wherein, R_1= O-alkyl(C_1-C_6), NH-alkyl(C_1-C_6), N(dialkyl(C_1-C_6)), alkyl(C_1-C_6)-O-alkyl(C_1-C_6), alkyl(C_1-C_6)-NH-alkyl(C_1-C_6) and alkyl(C_1-C_6)-N-(dialkyl(C_1-C_6)), R_1 and R_2 form a cycle, R_3= hydrogen, halogen, alkyl (C_1-C_2), cycloalkyl(C_3-C_6), alkenyl(C_2-C_6), alkynyl(C_2-C_6), -O-alkyl(C_1-C_6), haloalkyl(C_1-C_6), $S0_2R_4$, NH-R_4, NR_4R_5, CO-NHR_6, $COOR_6$, C(NR7)R_6, phenyl, substituted phenyl, heteroaryl and substituted heteroarylof any kind have been made or used.

(G) Skill of those in the art: The ordinary artisan is highly skilled.

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted groups on Formula i. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 6, 8-21, 24, 26-32 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dusza et. al. (US 4654347).

The instant Application claims compounds of formula (I), wherein R_3= carbonyl-thienyl, R_1= 4-methylphenyl and R_2= methyl and compositions thereof.

Dusza et. al. teaches compounds of formula (I), wherein R_3= carbonyl-phenyl, R_1= 4-methylphenyl and R_2= methyl and compositions thereof. Note, this compound is excluded by proviso by Applicant.

The difference between the instant Application and the reference is the substitution at the R_3 variable, carbonyl-phenyl versus carbonyl-thienyl. The genus in the reference in column 1 teaches the thienyl and phenyl are alternatively useable, see lines 40 and 66. The reference also teaches other heterocycles which renders the instant Application obvious. Furthermore, the reference teaches many overlapping substituents at R_1 and R_2. The compositions are found on page 12. Thus, Dusza et. al. renders said claims obvious.

Claims 1, 5, 6, 8-21, 24, 26-32 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dusza et. al. (EP 129847).

The instant Application claims compounds of formula (I), wherein R_3= carbonyl-pyridyl, R_1= 4-methylphenyl and R_2= ethyl and compositions thereof.

Dusza et. al. teaches compounds of formula (I), wherein R_3= carbonyl-furanyl, R_1= 4-methylphenyl and R_2= methyl and compositions thereof. Note, this compound is excluded by proviso by Applicant.

The difference between the instant Application and the reference is the substitution at the R3 variable, carbonyl-pyridyl versus carbonyl-furyl. The genus in the reference on page 1 teaches the furyl and pyridyl are alternatively useable, see page 2, line 7. The reference also teaches other heterocycles which renders the instant Application obvious. Furthermore, the reference teaches many overlapping substituents at R_1 and R_2. Thus, Dusza et. al. renders said claims obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
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